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U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460
Attention: Docket ID No. EPA–HQ–OPPT-2016-0401

Submitted electronically to www.regulations.gov

RE: Fees Under the Amended Toxic Substances Control Act

Dear Document Control Officer:

The International Fragrance Association North America (IFRA North America) and its members appreciate this opportunity to provide input to the Agency regarding its forthcoming rule on fees under the newly-amended Toxic Substances Control Act (TSCA).[1]

Background

IFRA North America is the principal trade association representing the interests of the fragrance industry in the United States and Canada. IFRA North America represents over 90% of all fragrances developed and sold in the two countries. Our member companies create and manufacture fragrances and scents for home care, personal care, home design and industrial and institutional products, all of which are marketed by consumer goods companies. IFRA North America also represents companies that supply fragrance ingredients, such as essential oils and other raw materials, used in perfumery and fragrance mixtures.

IFRA North America members are both manufacturers and processors of chemicals. In the former capacity, they both manufacture chemicals in the United States and import them from elsewhere. These chemicals may be fragrance ingredients, raw material building blocks used to make fragrance ingredients, or chemicals used in the manufacturing process, for example as solvents. Thus, IFRA North America has important interests, from a variety of perspectives, in the rules that EPA develops for implementing its new fee authority.

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[1] https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/meetings-and-webinars-amended-toxic-substances-control.

We first identify the policy considerations we regard as most important in this connection. We then offer some specific recommendations to effectuate those policy goals.

I. Policy Considerations

The new fee authority contained in Section 26(b) was widely supported by stakeholders as necessary, under the current budget climate, if EPA was ever to be able to meet the throughput obligations that the new amendments establish.

EPA needs to exercise care in establishing fees, however, to ensure that it does "not . . . impede unduly or create unnecessary economic barriers to technological innovation."[2] In particular, EPA must be careful to ensure that the fees do not maintain the prior law's bias toward existing chemicals. As former OPPT Director Charlie Auer wrote recently, "over the course of my EPA career, I came to see new chemicals as a source of continuous innovation in the introduction, over time, of progressively safer and greener chemicals. I encourage EPA to apply both the letter and spirit of new TSCA Section 2(b) to ensure that new chemicals continue to be healthy contributor to innovation."[3]

The new fee authority must also be fair. In particular, it must reflect the vast disparities among potential payors, both in terms of the size of the businesses and in terms of the volumes of chemicals that they may manufacture or process. Those volumes can easily vary by multiple orders of magnitude.

II. Specific Recommendations

PMN fees should not be increased substantially beyond the inflation-adjusted version of $2,500. As just noted, EPA should ensure that its fee structure promotes innovation by encouraging chemical innovation. Particularly given that about one-half of PMN chemicals never commence manufacture, the development of new chemicals can easily be affected by the cost of a PMN submission. It would be fair to increase the fee to whatever $2,500 in 1976 dollars would represent today. However, EPA should not go significantly above that amount.

We note, moreover, that fragrance processors generally do not accept chemicals produced under the low volume exception because of their desire to ensure that fragrance ingredients have indeed been reviewed by EPA and found not likely to pose an unreasonable risk. Since that exception is generally not available to our

[2] 15 U.S.C. § 2601(b)(3).
[3] "Old TSCA, New TSCA, and Chemical Testing," BNA ENVIRONMENT REPORTER (Aug. 15, 2016).

industry, it is all the more essential that EPA maintain PMN fees at a sufficiently low level.

IFRA North America agrees with the general sentiment that persons subject to Section 4 orders or rules should not be required to pay submission fees in addition to the costs they already have to incur to conduct required testing.

EPA should not inhibit innovation. Once a new chemical substance has been successfully notified under TSCA and included on the Inventory, it can be manufactured, imported or processed by anyone, without the need for them to file any further notification. As a result, the entire financial burden of the fees is on the original notifier. Therefore, the PMN fees should be kept at inflation-adjusted current levels so as not to create an overly unfair system for those willing to invest the time, resources and expense of notifying new chemicals.

EPA should not tie fees to uses. Since the safety standard of TSCA is no unreasonable risk under the reasonably foreseeable conditions of use – not those identified in a PMN or those intended by the manufacturer or processor – EPA should not tie fees to particular uses.

EPA should update the cutoff for "small business concerns." Currently, this term is defined as "any person whose total annual sales in the person's fiscal year preceding the date of the submission of the applicable section 5 notice, when combined with those of the parent company (if any), are less than $40 million."[4] This definition is decades old, and the dollar cutoff should at least be updated for inflation.

EPA should also not require submitters to substantiate their eligibility for these reduced fees, relying instead on a self-certification and the potential for criminal liability for making false statements to the government.[5] The benefit of reduced fee for small businesses would quickly be eliminated by any substantiation requirement.

EPA should establish volume-based fees. Fragrance manufacturers may very well represent the extreme end of the continuum when it comes to the amount of material that they manufacture or process. Fragrance ingredients are often detectable at ppm and even ppb levels in products. Thus, very small quantities of these ingredients can go a very long way. Fragrance manufacturers may literally only produce a few kilograms of a material in a year. A fee that is purely entity- or chemical-based would grossly discriminate against such businesses.

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[4] 40 C.F.R. § 700.43.
[5] *See* 18 U.S.C. § 1001.

EPA should not charge fees for CBI claims. IFRA North America also concurs with other industry representatives that EPA should not follow Canada's model and impose additional fees on submissions that include claims of confidential business information. Doing so would clearly create a bias against innovation. We believe it is appropriate and fair for CBI costs to be rolled into the overhead associated with the Section 4, 5 and 6 programs.

EPA should not attempt to model its fee authority on the pesticide or drug models. EPA's new fee schedule must be simple. We are aware that Congress and agencies have created user fee systems for pesticides and drugs under the Pesticide Registration Improvement Act (PRIA) and the Prescription Drug User Fee Act (PDUFA). These systems are horrendously complicated, however, and are tolerable only because the users receive an exclusive license to produce the product in question. That is not the case under Sections 5 or 6 of TSCA. EPA should not even consider these statutes as models for the TSCA fee system.

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IFRA North America appreciates this opportunity to provide input into the rulemaking regarding fees under amended TSCA. If you have any questions about these comments, or would like additional information, please do not hesitate to contact me at 571-317-1505 or shartigan@ifrana.org.

Respectfully,

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